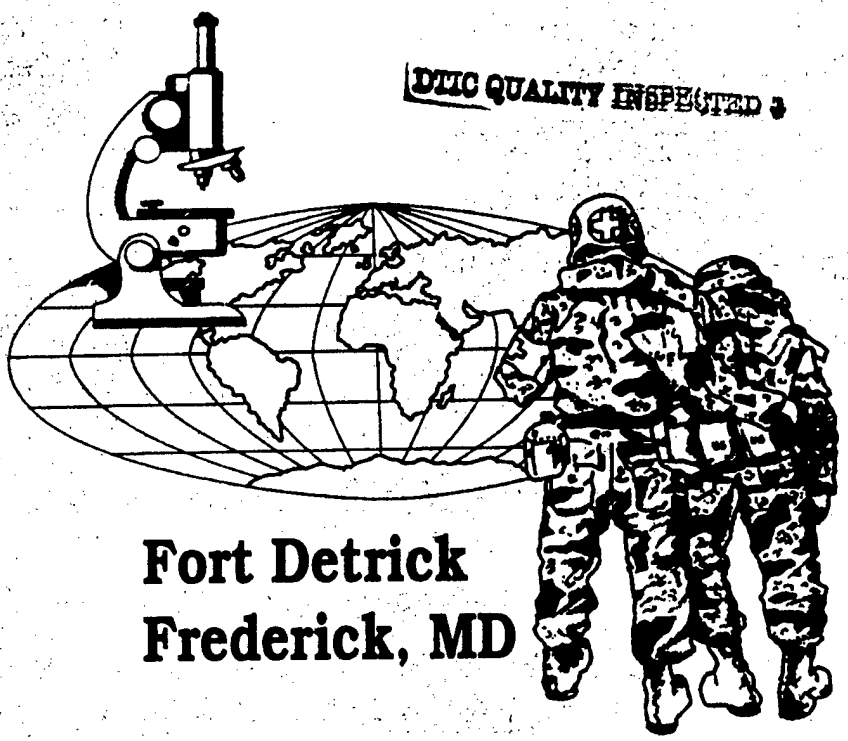
United States Army Medical Materiel Development Activity

1996 ANNUAL REPORT



Fort Detrick
Frederick, MD

1996 ANNUAL REPORT

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The Annual Report, Calendar Year 1996, summarizes development projects managed by the U.S. Army Medical Materiel Development Activity as authorized by The Surgeon General, the Commander, U.S. Army Medical Research and Materiel Command and supported by the RDTE funds from the Department of Defense.

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U.S. ARMY
MEDICAL MATERIEL DEVELOPMENT ACTIVITY
1996 ANNUAL REPORT
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MESSAGE FROM THE DIRECTOR

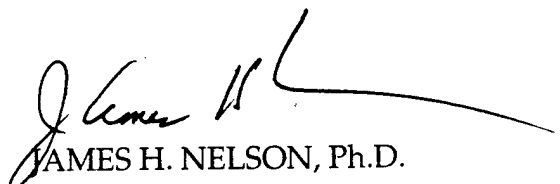
Friends and Colleagues,

On 29 August 1996, I enthusiastically accepted the challenge of leading the U.S. Army Medical Materiel Development Activity (USAMMDA) into the 21st Century. Ours is an organization with a fresh new outlook - one committed to new innovations in Medical Materiel Development - one that embraces new advanced technologies, streamlined management and innovative business practices. Our goal is to rekindle a spirit of cooperation with our partners - the U.S. Army Medical Research and Materiel Command (USAMRMC) and its many fine laboratories and activities, the U.S. Navy Medical Research and Development Command (USNMRDC) and its laboratories, the U.S. Army Medical Department Center and School, and our partners in industry and academia.

Today we are at a crossroads. We recognize that technology development and its shaping are absolutely key to our future. To succeed, we have to recognize the boundaries, but, more importantly, we must see the linkages among developments across a spectrum of fields. Winners cross boundaries, make connections, take risks and exploit new innovations. At USAMMDA, we have marshaled a combined force of acquisition professionals and outstanding scientists to create an organization which is committed to seizing the lead in Medical Materiel Development with an unsurpassed ability and dedication to bring superior products to the Soldier, Sailor, Airman and Marine.

We are dedicated to streamlining our workload and increasing the likelihood of success by removing from our roster, by transition or termination, those projects which have come as far as we can bring them. We will, instead, direct our energies to developing products with a high probability of successful fielding in a short time.

Our deep resolve is to accelerate and streamline the acquisition process to provide high-quality medical products to U.S. Forces. But we cannot - and should not - work alone. We will reach out, striking up increased partnerships with the USAMRMC and USNMRDC laboratories, the Research Area Directors, Readiness Activities, Procurement Activities, Combat Developers, Industry, Academia and any others with a stake in our commitment. There is increased power in teams, and the new USAMMDA will draw on the best minds, the best ideas and the benefits of cooperation through the synergy of integrated product teams, in order to fulfill our mission. I ask for your support and participation - I sincerely hope you will share my passion for excellence and join me in this New Beginning.



JAMES H. NELSON, Ph.D.
Director

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APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

THE PROGRAM

INTRODUCTION

The Applied Medical Systems Project Management Division is a multidisciplinary team with broad mission capabilities for the advanced development of medical products used to sustain and support the warfighters. The team consists of product managers, and model makers, who have expertise in project management, engineering, fabrication, and technical testing.

MILITARY RELEVANCE

The Applied Medical Systems Division designs, develops, and tests field medical equipment in support of battlefield combat casualties. The Applied Medical Systems Division specializes in adapting and hardening commercial off-the-shelf technology for joint military applications.

OBJECTIVES

The primary objective in 1996 was the early involvement of products that are within the technology base. New products in this category include Warfighter Personal Status Monitor (WPSM); Advanced Surgical Suite for Trauma Care (AZTEC); and Life Support for Trauma and Transport (LSTAT). A more focused objective was to maximize resources by leveraging technology; i.e., the Armored Medical Treatment Vehicle leverages the Command and Control Vehicle project for advanced development and testing. Leveraging allows us to streamline development efforts thereby combining Milestones and transitioning medical products rapidly to the logistician for procurement and fielding.

PRODUCT DESCRIPTIONS

First Priority Projects:

- The **Armored Medical Treatment Vehicle (AMTV)** is under development to improve identified shortcomings of M577A2 Battalion Aid Station (mobility, survivability, and ability to rapidly treat combat casualties). The AMTV is a derivative of the Command and Control Vehicle (C2V) on a Bradley-based chassis. The AMTV enclosure provides collective protection from chemical/biological agents, an environmental control system, and a separate power source for medical systems not

currently found in the M113 family of vehicles. An Integrated Product Team, consisting of the U.S. Army Medical Department Center and School (USAMEDDC&S), U.S. Army Medical Research and Materiel Command (USAMRMC), Program Executive Office for Ground Combat Support Systems, and United Defense Limited Partnership, developed a first generation prototype for participation in the Task Force XXI Advanced Warfighting Experiment (TFXXI AWE) scheduled for March 1997. The AMTV leverages a stable C2V program and uses elements of acquisition streamlining and technology insertion to accelerate the development process. The project is submitted as a potential Warfighting Rapid Acquisition Program (WRAP) candidate to continued funding for research and development.

- The **Life Support for Trauma and Transport (LSTAT)** is a mini-intensive care unit consisting of a self-contained evacuation platform for life support incorporating an on-board ventilator, suction unit, oxygen bottles, patient vital signs monitoring, and closed-loop therapeutic capabilities. The LSTAT interfaces with current military and civilian medical evacuation vehicles. The LSTAT integrated product team includes USAMRMC, the Defense Advanced Research Project Agency (DARPA), and Northrop Grumman. The project leverages commercial off-the-shelf technology to the maximum extent possible.

- The **Thawed Blood Processing System (TBPS)** is an automated pump driven deglycerolization filtration device that replaces the existing labor intensive Haemonetics 115 unit. The new device will reduce size and weight of the existing system by 75% and is expected to reduce disposable costs from approximately $135 to $60. The device employs a simple "pop-in cassette" and an automated microprocessor control system that simplifies the operator control to a single start button. Blood in the new system is totally isolated and closed by the peristaltic pumps and solenoid pinch valves to achieve sterility and attain a 3-week extendable shelf-life with the automatic addition of a blood additive. The manufacturer, Rasor Associates, and the Bethesda Naval Blood Research Laboratory will begin collecting data for a Food and Drug Administration (FDA) 510(k) device approval in 3QFY97.

- The **Medical/Dental Filmless Imaging System (MDFIS)** consists of an image acquisition system, and an imaging workstation. These will replace film and chemical processing equipment in current applications. The product leverages off-the-shelf technology and reduces the logistical burden associated with radiology film technology. A final product specification for the dental application is ongoing. The product is expected to transition to the logistician for deployment in 1997.

- The **Field Triage Light (FTL)** is powered by a rechargeable battery for use in the triage area of field treatment operations. The light is a man-portable package containing a battery that will provide 8 hours of uninterrupted power, a 110/220 volt

recharging circuit, and cables that can provide alternative power to the light; e.g., vehicle battery power. A prototype was designed and fabricated at USAMMDA and sent to the USAMEDDC&S for an early user evaluation in November 1996. After evaluation, the combat developer will decide if the prototype is suitable and commit to an operational requirement document, or a technology watch will be initiated to search for a commercial source.

- The **Far Forward Suction Apparatus (FFSA)** is a portable multipurpose device capable of both continuous and intermittent modes over a wide range of vacuum levels. The device is designed for multiple power sources including a self-contained battery and universal receptacle to a myriad of collection containers. In a joint effort with the Air Force, the prototype unit is undergoing air worthiness testing at Brooks Air Force Base. The IMPACT Model 326 recently received FDA approval and has a commercial market.

- The **Electrochemical Sterilization System (ESS)** is a sterilizer system using concentrated ozone generated by an advanced electrochemical cell. The system provides a means of rapidly sterilizing heat or moisture sensitive items in field hospitals. Unlike liquid sterilants, ozone sterilization is a dry process that allows the use of wrappers that preserve the sterilized goods. The first prototype was built using the Small Business Innovative Research (SBIR) contract, and the company is seeking a commercial partner to pursue Phase 3 SBIR completion tasks.

- The **Advanced Surgical Suite for Trauma Casualties (AZTEC)** is a rapidly deployable structure capable of providing trauma management, resuscitative surgery, ancillary services, and temporary patient holding. This surgical suite is a compact, modular structure that quickly expands to post-operative care to evacuation for Echelon II Level deployment. A 6-week Phase I contract was awarded to Oak Ridge, TN, Department of Energy Laboratory, in December 1996, to do the preliminary AZTEC design.

- The **Combat Stress Analysis (CSA)** system will conserve manpower resources and maximize performance by identifying and minimizing stress before it becomes catastrophic. Galvanic skin resistance is being used as an indicator of stress in academia and industry. The technology watch maintains cognizance over this and similar efforts and will be used to recommend off-the-shelf procurement when products reach the marketplace.

- The **Warfighter Personal Status Monitor (WPSM)** is a wireless wrist-worn watch-like sensor platform and a separate executive control unit (ECU) containing the warfighter's Meditag. This system will not be a stand-alone fieldable medical system, but will be integrated into and utilize the Force XXI Land Warrior computer/

communication system for its global positioning system and "Distress Call" capabilities. The ECU provides the interface between the sensor platform and Force XXI Land Warrior computer/communication system and Meditag. The sensor platform provides a long term monitoring capability that can be worn during combat and noncombat, and supplemented by independent mission-specific wireless sensor appliques; e.g., climate or altitude extremes, toxic hazards, etc.

- The **IV Fluids Warmer (IVFW)** is a far forward lightweight intravenous fluids warmer/infusion device for use by combat medics and on evacuation platforms in the field. The device will include a simple fusion feature and a lightweight heat source such as a microwave or perhaps butane. A device that meets the general requirements is about to be developed by a small business organization under the Broad Agency Announcement contract mechanism.

- The **Expert System for Trauma Management (ESTM)** is a technology watch of industry and university efforts in Artificial Intelligence and Expert Systems with the objective of leveraging the technology for use in combat advanced trauma management applications. A demonstration of this technology is underway using a commercial vital signs monitor.

Technology Watch:

- The **Low Temperature Sterilizing System (LTSS)** is a prepackaged dry-powdered chemical sterilant that is added to potable water to effect rapid sterilization of surgical instruments. This product will replace glutaraldehyde which requires over 8 hours immersion time, is toxic, environmentally unacceptable, and is less than optimally effective. Problems encountered with in-use testing required for regulatory submission have delayed completion and, therefore, shifted the FDA submission; specific target dates are unknown. The Phase 2 SBIR with STERIS was terminated and a technology watch instituted to maintain cognizance over this effort and to recommend off-the-shelf procurement when the product reaches the marketplace.

- The **Self-Contained Ventilator (SCV)** is a powered, individually operated ventilatory assistance device for use on casualties in forward areas (Echelon I and II) and during evacuation. A joint initiative with the Air Force, units are undergoing Air Worthiness and technical testing at U.S. Army Aeromedical Research Laboratory and Aeromedical Research Laboratory, Brooks Air Force Base.

- The **Portable Field Oxygen Concentrator (PFOC)** is a lightweight, man-portable oxygen concentrator ruggedized for field use, which will produce high purity oxygen at a minimum flow of three standard liters per minute. The unit replaces "D" cylinders during patient transport and treatment. The concentrator will be powered by battery or

line power and will require FDA approval prior to adapting technology for military applications. Ceramic and proton membrane exchange oxygen generators are being developed for military and commercial applications. An Integrated Product Team was formed to leverage these technologies as they mature.

- The **Intraosseous Infusion Device (IID)** is a medical device for rapid administration of IV fluids in the bone marrow as an alternative to vascular access for severe shock treatment. The intraosseous infusion device allows placement of a rigid needle into non-collapsible bone for the infusion of fluids and medications directly into bone marrow. The project is currently in technology watch.

Transition to Logistician:

- The **Field Anesthesia Machine (FAM)** is a compact, state-of-the-art upgrade to or replacement for the Ohmeda Model 885A FAM. Development was delayed due to funding cuts for telemedicine enhancements. Subsequently, a low-level tech base funded effort to produce a new small lightweight prototype was successfully accomplished at Walter Reed Army Institute of Research (WRAIR). This tech base effort spurred two major anesthesia machine manufacturers to independently develop two new prototypes. All three new machines were evaluated clinically and found acceptable. Essential characteristics were updated for procurement, and the Defense Medical Standardization Board is planning an NDI standardization.

- The **Liquid Oxygen Production, Storage and Distribution System (LOPSDS)** is a transportable, centralized Liquid Oxygen (LOX) production and storage system that generates LOX in the Corps and Echelons Above Corps. Bulk tanks (100 to 400 gallon) are used to transport LOX to tactical hospitals. The LOX is vaporized into gaseous oxygen to fill pressurized oxygen cylinders or for distribution to operating rooms and patient wards.

MAJOR ACCOMPLISHMENTS

- A prototype **AMTV** was manufactured by United Defense Limited Partnership (UDLP) under contract from Tank-Automotive and Armament Command (TACOM), and delivered to the 4th Infantry Division at Fort Hood, Texas, for participation in TFXXI AWE.

- Initiation of Technical Testing of three subcomponents of the **LSTAT** (suction unit, vital signs monitor, and defibrillator). Identification of the prototype ventilator, infusion pump, and blood chemistry. A correspondence Milestone 0 IPR was initiated December 1996.

- Design of a second generation **TBPS** prototype device to replace the existing Haemonetics 115 system was accomplished in 1996. Successful testing of the prototype was conducted at the Naval Blood Laboratory in Bethesda, Maryland. The test data indicated that the prototype is capable of satisfying all FDA requirements for blood chemistry including removal of both the cryoprotectant glycerol and plasma free hemoglobin. The device is fully automated and a 75% reduction in size and weight compared to the Haemonetics 115. It will also reduce the cost of the disposable from the current $135 to approximately $60.

- Six commercial dental-size filmless systems have become available during the last year, and five companies have prototypes of medical-size systems that meet MDFIS requirements, which the companies say will be available by the end of the year. Efforts are underway to write performance specifications which will permit commercial off-the-shelf procurement. This will be completed by end of FY97.

- The **FTL** was fabricated and tested for technical performance. It is currently undergoing User Tests at Fort Sam Houston, Texas.

- The Impact Model 326 **FFSA** has been identified by both the Army and Air Force as the best commercial device to satisfy all military requirements for the field, particularly the dual mode specification. The device has been approved by the FDA and put into initial production. Aeromedical testing is currently being conducted at both the U.S. Army Aeromedical Research Laboratory (USAARL), and Brooks Air Force Base. In addition, clinical testing is being conducted by the Hancock County (Tennessee) Emergency Rescue Squad.

- The Research Area Director, Combat Casualty Care requested program management support from USAMMDA for **AZTEC** project on 23 August 1996. A Market Investigation was initiated and engineering resources identified.

- An **ESTM** system based on fuzzy logic has been applied to vital signs monitoring. The program presents the information from eight digital readouts in normalized graphs. This makes variations from acceptable values readily apparent. In addition, it will identify trends in the data and warn of approaching disaster so intervention can be initiated early.

- Administrative transition of the **LOPSDS** project to USAMMA was accomplished in March 1996. USAMMA picked up responsibility for the final actions necessary to begin fielding the system. The Oxygen Hazard Analysis with NASA, the LOX contractor, and members of the U.S. Army Medical Department was conducted during the period of 5-7 March 1996. The final report was forwarded to USAMMA for appropriate action.

PROJECTIONS

- Following TFXXI AWE, the **AMTV** prototype will be retrofitted by the contractor to allow users to reconfigure the vehicle to either the evacuation or treatment mission configuration. A Concept Evaluation Plan test will be conducted on the treatment configuration. A Milestone I/II is projected for 3QFY97.

- An Operational Requirements Document (ORD) for the **LSTAT** will be drafted at USAMEDDC&S. Technical Testing is scheduled for the four "Test and Evaluation" prototypes. The first prototype units are scheduled to undergo airworthiness testing. The unit is expected to have early developmental and operational testing at Fort Irwin, California, in support of the National Training Center Rotations in June 1997.

- The development contractor will fabricate the Model A **TBPS** (does not include 2-week storage) and initiate data collection for the 510(k) FDA submittal.

- The **MDFIS** will transition to the logistician for production and fielding in 1997.

- Evaluate results of **FTL** User Testing. Obtain a requirements document or commitment from the combat developer or initiate technology watch for a commercial item.

- USAMMDA will evaluate **FFSA** test report findings by both USAARL and the Air Force and transition the device to USAMMA if found to satisfy all military requirements.

- The **ESS** technology watch will continue.

- An ORD for the **AZTEC** will be drafted at USAMEDDC&S. A phased engineering effort at Oak Ridge National Laboratories was initiated. Phase 1 includes Conceptual Design and Analysis, and Phase 2 will include detailed design, construction of a mock-up, and pre-production planning. Phase 3 will be initiated 3QFY97 and will include the manufacture of the first prototype.

- The **CSA** technology watch will continue.

- The **WPSM** is currently in the technology base and is expected to transition to concept exploration (Post Milestone 0) activities within the next 17 months for advanced development.

- The **ESTM** technology watch will continue.

APPLIED MEDICAL SYSTEMS
PROJECT MANAGEMENT DIVISION

INDUSTRIAL SERVICES BRANCH

INTRODUCTION

The Industrial Services Branch (ISB), Applied Medical Systems Project Management Division, is a small team of craftsmen model makers possessing at least two trade skills who design, develop drawing packages, and rapidly prototype medical equipment in support of USAMRMC. The Branch is capable of rapidly prototyping medical devices in a range of scales and variety of materials and can also harden commercial off-the-shelf equipment for use in a field environment.

In FY96, 65 service requests were completed by the ISB. About 86% of the tasks were in support of the design and fabrication of prototypes for the AMTV and FTL. Other organizations supported by ISB and the specific number of projects and the hours spent on the projects from each are listed below:

Organization	Projects	Hours
USAMRMC	25	460
USABRDL	5	115
USAMRIID	1	234
USAG	2	8
WRAIR	2	8
MATMO	4	103
AEHA	1	30
USAMRICD	3	10
USAMMA	8	36
OTHER	2	4

PHARMACEUTICALS SYSTEMS
PROJECT MANAGEMENT DIVISION

INTRODUCTION

The Pharmaceuticals Systems Project Management Division centrally manages the development and acquisition of pharmaceutical and biological products (drugs, vaccines, toxoids), related drug delivery systems (e.g., autoinjectors), resuscitative fluids, and skin protectants. These products are fielded as preventive, protective and therapeutic modalities for use against infectious disease, chemical and biological warfare threats, and for the treatment of combat casualties. Product managers leverage domestic and foreign medical technology to remedy deficiencies identified by the Combat Developer and monitor military research projects for potential solutions to identified problems.

MILITARY RELEVANCE

U.S. Military forces must be prepared to serve anywhere in the world against any threat. This could result not only in conventional injuries sustained during combat operations but exposure to chemical and biological warfare agents as well as exposure to endemic diseases not commonly found in the United States. The development of products against these threats will help save lives, sustain the fighting force and enhance return to duty.

OBJECTIVES

This Division's objective is to develop safe, effective products to be used for prophylaxis, immediate treatment, or definitive treatment of a wide variety of naturally occurring diseases, exposure to chemical and biological agents, and combat injuries. These products include those used for prophylaxis and treatment of botulism exposure, pretreatment and treatment of nerve agent exposure, topical skin protection against percutaneous chemical threat agents, a new multichambered autoinjector which will improve the delivery of nerve agent antidotes, and rapid methods to identify biological threat agents in clinical samples. Additionally, drugs and vaccines are under development to protect against or treat malaria, diarrheal diseases (cholera, shigellosis), meningitis, hemorrhagic fevers, and leishmaniasis.

PRODUCT DESCRIPTIONS

- **Antimalarial Drug WR 238,605** is an 8-aminoquinoline derivative that has demonstrated antimalarial potential in preclinical studies. It is being developed as a replacement for primaquine for the prophylaxis and treatment of malaria.

- **Antimalarial Drug, Azithromycin** is an azalide, a subclass of macrolide antibiotics, similar to erythromycin. It is a U.S. FDA approved oral medication manufactured and marketed by Pfizer, Inc., for the treatment of respiratory tract infections. It has antimalarial activity in both *in vitro* and *in vivo* drug evaluation systems. The product is being developed as an alternative to doxycycline for the prophylaxis of malaria.

- **Antimalarial Drug, Halofantrine, Prophylactic** is a 9-phenanthrene-methanol compound. It is a U.S. FDA approved drug for the treatment of malaria. It is being developed as an alternative to chloroquine and mefloquine for the prophylaxis of malaria.

- **Detoxified LPS-OMP Meningococcal Group B Vaccine** consists of noncovalent complexes of purified meningococcal outer membrane proteins (OMP) and alkaline detoxified meningococcal liposaccharide (LPS). This vaccine is being developed for the prevention of meningitis due to *Neisseria meningitidis* Group B.

- **Tick-Borne Encephalitis Virus (GERMAN-BPL# 366) Vaccine (TBE)** is an inactivated viral vaccine for prevention of Central European Encephalitis (CEE), which occurs in several European countries, as well as Russia and China.

- **Tick-Borne Encephalitis Virus (AUSTRIAN-BPL# 335) Vaccine (TBE)** is an inactivated viral vaccine for prevention of Central European Encephalitis (CEE), which occurs in several European countries, as well as Russia and China. While this vaccine is no longer in development, it is being used to vaccinate U.S. personnel in Bosnia.

- **Topical Skin Protectant (TSP)** is a perfluorinated formulation, which, when spread on the skin, forms a thin and breathable film surface capable of significant protection against percutaneous penetration of some chemical and biological warfare agents. Doctrinally, TSP is to be used as an adjunct to mission-oriented protective posture gear, not as a replacement.

- **Hantaan M-S (Vaccinia Vectored) Vaccine** is a live vaccine engineered at the U.S. Army Medical Research Institute of Infectious Diseases, was prepared by inserting the genes which code for Hantaan antigens into the live vaccinia virus carrier (smallpox vaccine). The resulting recombinant vaccine elicits antibodies against both vaccinia and Hantaan viruses.

- **Cholera Whole Cell Plus B Subunit Vaccine** is a combination killed, whole bacterial cell and B cholera toxin subunit oral vaccine for prevention of diarrheal and systemic illness caused by *Vibrio cholera* infections. Field studies suggest that the B subunit also affords some protection against enterotoxigenic *Escherichia coli* (ETEC), a common cause of diarrheal disease. The vaccine is being tested against both indications in collaboration with the Naval Medical Research Institute (NMRI).

- **Enterotoxigenic *E. coli* (ETEC) Vaccine** is an oral vaccine prepared from several strains of inactivated whole bacterial cells plus the B subunit of the cholera toxin. This vaccine is manufactured by the SBL Vaccin AB (Sweden) and is being tested in collaboration with the NMRI and the manufacturer.

- **Argentine Hemorrhagic Fever (AHF) Live Vaccine** is an attenuated vaccine for military personnel being deployed to areas where AHF is endemic. The vaccine was prepared by growing the virus in fetal rhesus monkey lung cells in a collaborative effort between USAMRIID and the Salk Institute.

- **Nerve Agent Pretreatment, Pyridostigmine (NAPP)** is a cholinesterase-inhibiting drug which is used prophylactically to mitigate the risk of mortality from use of nerve agents. Studies show that prophylactic use of NAPP considerably enhances the efficacy of the standard nerve agent antidotes (atropine + 2-pralidoxime).

- **Hypertonic Saline Dextran (HSD)** is a safe and effective small-volume resuscitative fluid, suitable for rapid field administration to stabilize hypovolemic shock casualties. A Cooperative Research and Development Agreement (CRDA) has been established with Medisan Pharmaceuticals for the development of this product.

- **Cyanide Pretreatment (CP), WR242511** is an 8-aminoquinoline methemoglobin-forming compound being developed as an oral prophylaxis for cyanide poisoning. Data suggest that this regimen will protect against the lethal effects of two times the LD_{50} (the dose which results in 50% deaths in the exposed group) of cyanide.

- **Campylobacter Vaccine** is a killed, whole cell oral vaccine adjuvanted with heat labile toxin from *Escherichia coli*. The vaccine is designed to protect against diarrhea and systemic illness caused by gram-negative bacteria of the genus *Campylobacter*.

- **Chikungunya Live Vaccine** is an attenuated vaccine which prevents fever, headache, and severe joint pain caused by Chikungunya virus. It is designed for administration to military personnel prior to deployment to endemic areas worldwide.

- **Schistosome Topical Antipenetrant (TAP)** is a niclosamide-based skin lotion that is designed to prevent schistosome infection. The lotion applied on the skin will prevent the penetration of free swimming infectious schistosome larva.

- **Rift Valley Fever Live Vaccine** is an improved vaccine that will provide immunity with a single dose rather than the three doses required for the current inactivated vaccine. The vaccine will provide greater protection in a shorter amount of time to Servicemembers operating in geographic areas where there is high risk of infection with Rift Valley Fever.

- **E. coli Vectored S. Flexneri Shigella Vaccine** is an oral vaccine produced by inserting genes for *Shigella flexneri* antigens into an *Escherichia coli* vector. This bioengineered vaccine was developed at WRAIR and produced at the Salk Institute.

- **Antimalarial Drug, Arteether** is an antimalarial drug that is a derivative of the Chinese herbal remedy Qinghaosu. It has been shown to inactivate malaria parasites in cell cultures, animal model test systems and in man. It is intended as an expedient, intramuscularly injected treatment for severe and complicated multi-drug resistant malaria. Without the availability of this drug, fatality rates among nonimmune adults could exceed ten percent.

- **Nerve Agent Antidote, Multichambered Autoinjector** is a single-barreled, dual-chambered autoinjector that injects the nerve agent antidotes, atropine and 2-pralidoxime, through a single needle. It is being developed as a replacement for the MARK I Nerve Agent Antidote Kit, which requires two separate injections.

- **Leishmania Skin Test** is a formalin-killed promastigote antigen used for screening of soldiers who may have been exposed to *Leishmania spp.* The antigen was produced under current Good Manufacturing Practices (cGMP) by the Biologics Research Department at the Walter Reed Army Institute of Research.

- **Antileishmanial Drug WR 6026** is an 8-aminoquinoline derivative developed as an oral treatment for visceral leishmaniasis.

- **Malaria Recombinant Vaccine with Adjuvant Combinations** is a vaccine for the prevention of *Plasmodium falciparum* infections. The vaccine consists of recombinantly engineered immunogenic fractions of the malaria sporozoite surface coat coexpressed with protective epitopes from the hepatitis B surface antigen. The vaccine is formulated in a liquid emulsion containing potent immunostimulants.

- **Tularemia Live Vaccine** is an attenuated vaccine for military personnel being deployed to an area where there is a potential threat use of *Francisella tularensis.*

- **Cell Culture Derived Vaccinia - Live Vaccine** is a cell culture produced vaccinia vaccine to protect against smallpox. This is a cleaner product than the calf lymph vaccine produced by Wyeth, Lederle.

- ***Clostridium Botulinum* Toxoid, Pentavalent (Types A,B,C,D,E)** is a toxoid vaccine produced from the specific monovalent toxins of *C. botulinum*, serotypes A,B,C,D, and E, and blended into a pentavalent product. It is produced by the Michigan Biologics Products Institute (MBPI) (formerly Michigan Department of Public Health (MDPH)). Its intended use is for prophylaxis of soldiers against botulism due to aerosol exposure of the aforementioned toxin serotypes.

- ***Clostridium botulinum* Type F Toxoid** is a toxoid vaccine produced from the toxin of *C. botulinum* serotype Type F. It is an IND product produced by the Centre for Applied Microbiology and Research, Porton Down, U.K. Its intended use is for prophylaxis against botulism due to aerosol exposure of the toxin, serotype F.

- ***Clostridium botulinum* Type G Toxoid** is a toxoid vaccine produced from the toxin of *C. botulinum* serotype Type G. It is produced by the Centre for Applied Microbiology and Research, Porton Down, U.K. Its intended use is for prophylaxis against botulism due to aerosol exposure of the toxin, serotype G.

- **Q Fever CMR Extract Vaccine** is a purified formalin and gamma irradiation inactivated vaccine prepared at the Salk Institute. Extraction of the infected yolk sacs with chloroform-methanol is believed to render the vaccine less reactogenic.

- **Botulism Immune Globulin $F(ab')_2$ Heptavalent Equine** is an equine antitoxin to be administered intravenously for treatment of botulism. This antitoxin is prepared by fractionation of plasma from hyperimmunized animals. This equine heptavalent (ABCDEFG) preparation should be a broadly effective treatment (because it is heptavalent) for botulinal intoxication. The manufacturing process for this product is designed to minimize the risk of serum sickness and other complications associated with other horse-protein derived products.

- **Botulism Immune Globulin (Human)** is a human immunoglobulin used in the treatment of botulism. It was prepared by fractionation of plasma from volunteers immunized with pentavalent botulinum toxoid. It was developed for the prophylaxis or therapeutic treatment of botulism caused by serotypes A,B,C,D, or E.

- **Vaccinia Immune Globulin (VIG)** is used to treat vaccinia complications resulting from immunization with investigational vaccinia vectored vaccines, use of vaccinia as a smallpox vaccine, or to treat cases following offensive use of smallpox virus. The VIG manufacturer uses plasma from immunized volunteers to ensure a product that exhibits potency required for a licensed product.

- The **Diagnostic Kit for Biological Warfare Agents** is a rapid system for use in a field medical laboratory for rapid identification of biological warfare agents from clinical samples obtained from exposed personnel. The kit will be used as a screening method to provide rapid information to the medical care provider that can be later confirmed using more sensitive technologies.

- **Ricin Toxoid Vaccine** is being developed to protect Servicemembers against the potential Biological Warfare agent Ricin. This vaccine is a formalin inactivated toxin, adsorbed to alhydrogel under current Good Manufacturing Practices (cGMP) by the Salk Institute.

- **Antimicrobial Dermal Dressing (ADD)** is a wound dressing capable of providing a sustained release of antimicrobial agent(s) at the site of superficial injuries to prevent infection and protect against the external environment.

DEVELOPMENT FACILITIES

- **University of Maryland Vaccine Testing Facility** conducts Phase 1 Safety and Phase 2 Safety and Efficacy Studies of vaccines. This facility is the only university vaccine center in the world engaged in the full range of vaccinology - from basic science through vaccine development, clinical evaluation and field studies.

- The mechanism of an Interagency Agreement between the FDA and the USAMRMC is being utilized for a **Contingency Vaccine Storage Facility** located at the FDA's National Center for Toxicological Research.

- **South Florida Drug Research Corporation** conducts Phase 1 clinical studies on candidate pharmaceutical products. These studies evaluate the pharmacokinetics, pharmacodynamics, tolerated dose levels and associated side effects of each tested product. Studies are done in a 60 bed clinical facility or on outpatients. Each study is performed under a specific task order and detailed in accordance with protocol.

- The **University of Illinois at Chicago, Non-Clinical Toxicology Contractor,** conducts toxicology studies on candidate pharmaceutical products. These Good Laboratory Practices (GLP)-compliant animal studies are required by the FDA to support Investigational New Drug Applications (INDs) and New Drug Applications (NDAs). Each study is performed under a specific task order and in accordance with a detailed protocol.

- **Salk Vaccine Production Facility** is a manufacturing and storage facility dedicated to the development and production of investigational vaccines and diagnostic reagents under federal regulatory guidelines. The primary customer of this facility is the DOD.

• **Michigan Biologic Products Institute** is currently the only responsible establishment licensed to manufacture **Anthrax Vaccine, Adsorbed (AVA)** in the United States. This is a sterile product produced from filtrates of an avirulent, nonencapsulated strain of *Bacillus anthracis*, which elaborates protective antigen during the growth period. The product was licensed by the Food and Drug Administration (FDA) in 1970. Testing is performed on each lot and results reviewed by the FDA prior to release for human use.

MAJOR ACCOMPLISHMENTS

• A Phase 2 treatment study of **WR 238,605** was initiated in Thailand during 4QCY96. A drug interaction study in animals continued at Southern Research Institute. Several toxicology studies (6 month rodent tox, Segment I, II and III teratology studies in rodents) were completed during CY96, and a one-year long-term toxicology study (dog) was initiated during 1QFY96.

• A Phase 2/3 field study of the prophylactic efficacy of **Azithromycin** against multi-drug resistant malaria in Thailand was continued. A Phase 3 pivotal field study on malaria prophylaxis was initiated in Irian Jaya, Indonesia.

• A Phase 1 safety study of **Halofantrine** for prophylaxis of malaria was conducted at Georgetown University Medical School. Nonclinical drug interaction/metabolism studies were completed at Georgetown University Medical School. Halofantrine isomer activity studies were also completed.

• CRDA Negotiations continued with the German manufacturer of the **Tick-Borne Encephalitis Virus (GERMAN-BPL# 366) Vaccine** to finalize pricing policy between the manufacturer and the Command.

• **Tick-Borne Encephalitis Virus (AUSTRIAN-BPL# 335) Vaccine** was used to vaccinate ~ 4,000 troops in Bosnia considered most at risk of infection by the virus.

• A clinical study showed that the use of **Topical Skin Protectant (TSP)** did not impair heat exchange or decrease tolerance time during exercise. An efficacy study in rabbits showed that **TSP** provided protection against VX, a nerve agent, for four hours as indicated by lethality and acetylcholinesterase (AChE) activity and against thickened soman (TGD) as indicated by **AChE activity**. Another study was completed in which it was demonstrated that N,N-diethylmtoluamide (DEET) reduced **TSP** effectiveness against sulfur mustard, HD, but removing DEET with a dry gauze partially reversed the DEET effects. A clinical efficacy study was initiated to demonstrate protection against poison ivy contact dermatitis, a surrogate to chemical warfare agents challenge model. A contract was awarded to McKesson Bioproducts for the final development of the **TSP**.

- A new lot of the **Hantaan M-S (Vaccinia Vectored) Vaccine** has been produced and the lot release data sent to the FDA. Volunteers receiving the vaccine developed measurable titers against both Hantaan virus and against smallpox virus. However, those volunteers who had previously received the smallpox vaccine failed to develop a titer against Hantaan virus. Therefore, this vaccine has limited military use.

- A CRDA has been signed by the manufacturer of the **Cholera Whole Cell Plus B Subunit Vaccine**, SBL Vaccin AB, and the Command, in which $350,000 will be paid to the Command. In turn, the Command will relinquish sponsorship of the IND to the manufacturer, who will submit to the FDA for licensure in the U.S. A special IPR package has been prepared recommending this change in sponsorship. A revised analytical plan for the pivotal efficacy trial in 20,782 volunteers in Lima, Peru, has been completed and submitted to the FDA for their comments.

- Preparatory to an efficacy trial for **Enterotoxigenic *E. coli* (ETEC) Vaccine** in Egyptian infants, Phase 2 safety and immunogenicity trials were performed in adults, school-age children, and toddlers.

- A clinical safety and immunogenicity trial was successfully completed for the last lot of a three-lot consistency trial for **Argentine Hemorrhagic Fever Live Vaccine,** antecedent for finalization of a PLA and ELA for this vaccine to be submitted to the FDA.

- The revised New Drug Application (NDA) for the **Nerve Agent Pretreatment Pyridostigmine** was filed with the FDA on 24 May 1996. Numerous requests for information were handled for the Gulf War Veteran's Illnesses Presidential Advisory Committee for the Office of The Surgeon General and for Congressional members. Several mutagenicity tests were conducted; overall, Pyridostigmine Bromide (PB) was found to be non-mutagenic.

- The CRDA partners have worked closely with the FDA to obtain guidance on submission of **Hypertonic Saline Dextran** covariant meta-analysis data. This data and c GMP practice data were submitted to the FDA as an addendum to the HSD New Drug Application submission.

- *In vitro* rat and human liver metabolism studies were completed for **Cyanide Pretreatment**. Training of non-human primate test subjects began for the serial-probe recognition study. The draft Investigational New Drug (IND) document was circulated and reviewed; the final draft IND is in preparation. An oral fertility and early embryonic development study in rats and a 13-week oral toxicity with recovery study in dogs were completed.

- A lot of improved altered adjuvant (mutant LT) to be used with the **Campylobacter Vaccine** has been prepared and an IND submitted. Phase 1 clinical trials at USAMRIID have determined the optimal dose of the adjuvant. The vaccine has been combined with the new adjuvant, an IND for the adjuvanted vaccine submitted to the FDA, and safety/immunogenicity trials are underway at USAMRIID.

- Clinical studies were initiated to obtain additional safety and immunogenicity data for **Chikungunya Live Vaccine**.

- It was determined, through Scientific Steering Committee and follow-up discussions, that a definitive human efficacy study using the **Schistosome Topical Antipenetrant** lotion is unfeasible. Alternate formulations recommended by CDC are not desired for military use, and the program is currently unfunded because of budget cuts. Therefore, we are pursuing the possibility of a technology transfer before recommending the termination of the program.

- **Rift Valley Fever, Live Vaccine** development was kept as an unfunded requirement.

- Due to lack of protection after challenge, there will be no further development of the ***E. coli* Vectored *S. flexneri* Shigella Vaccine.**

- Milestone I In-Process Review for **Arteether** was conducted in 1QCY96. Arteether was transitioned to Program Definition and Risk Reduction Phase of development.

- The FDA approved the regulatory filing of a 505(b)(2) for the **Multichambered Autoinjector**. That filing requires clinical bioequivalence data but does not require clinical efficacy data. The Nerve Agent Antidote, Multichambered Autoinjector development contractor is currently updating cost and schedules to complete the program. The revised information is due 31 January 1997.

- The IND for the **Leishmania Skin Test Antigen** was filed at the FDA in June 1996.

- A Phase 2 efficacy trial of the antileishmanial drug **WR 6026** continued during 1996. The purpose of the trial is to determine the most efficacious dose. In the most recent cohort completed, 2/3 of the subjects were cured of their visceral leishmaniasis by the test drug. A Segment I teratology study (rabbits) was completed. No teratogenic or other effects were seen.

- **Tularemia Live Vaccine** will continue to be used under IND status for immunization of at-risk personnel.

- PerImmune, Inc., completed plasma collection for future needs of the **Botulism Immune Globulin F(ab')$_2$ Heptavalent Equine**, conducted animal intraperitoneal efficacy testing, validated the GMP manufacturing facility, produced 28 monovalent batches and manufactured, vialed and lyophilized one heptavalent batch of antitoxin. PerImmune, Inc., also prepared a draft IND package with two clinical protocols, one for the safety and pharmacokinetic analysis of the product, and another for use of the product in an emergency treatment situation.

- In a double-blind, placebo controlled Phase 1/2a laboratory mosquito challenge study, the **Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combination** protected 86 percent of the volunteers. All volunteers who received the vaccine, even those who were not protected from *Plasmodium falciparum,* also produced high levels of protective antibodies to the Hepatitis B Virus. In July 1996, a combination MS 0/I was conducted that moved this product into advanced development. A second Phase 2 study was started that will be completed in 1QCY97 to verify the first study prior to conducting a Phase 2b study in Kenya.

- A Milestone I In-Process Review completed in 2QCY96 terminated the advanced development of the **SPf66 Malaria vaccine** because of lack of efficacy.

- The FDA approved a new lot of **Vaccinia Immune Globulin.**

- A Phase 2 safety test of the vaccine in skin-test positive volunteers continued to determine if the **Q Fever CMR Extract Vaccine** can be used without a Q fever skin test.

- The **Cell Culture Derived Vaccinia - Live Vaccine** demonstrated excellent protection in monkeys against monkeypox, a surrogate test for protection of humans against smallpox.

- A post marketing survey for **Plague Vaccine,** licensed by Greer Laboratories, was initiated at Schofield Barracks, Hawaii.

- Meetings were held with the FDA and USDA which generated input to the regulatory strategy for both human use and veterinary use indications for the **Diagnostic Kit for Biological Warfare Agents**. A draft Analysis of Alternatives was completed which analyzed risk factors, operational effectiveness, and life cycle costs.

- For **Botulism Immune Globulin (Human),** two new human use protocols were submitted during this reporting period; one under U.S. Army IND 1332, entitled "Administration of Pentavalent Botulinum Immune Globulin (Human) (An Emergency Use Protocol)" and one prepared by the FDA (IND 6750) entitled "Use of

Botulism Antitoxin (BAT) in the Event of Concurrent Poisoning of Many Individuals (Greater than 50 Individuals)." This product was also included in the development of serological endpoints of protection (toxin-neutralizing antibodies) in place of human efficacy studies.

- The Phase 1 safety protocol for the **Ricin Toxoid Vaccine** was placed on clinical hold by the FDA in 1995. In view of the development status of the **Ricin A Chain Vaccine** candidate, the decision was made to inactivate the subject IND.

- The **Antimicrobial Dermal Dressing (ADD)** program was terminated in 1QCY96 through a Special In-Process Review. The Army Medical Department (AMEDD) no longer had a requirement for the ADD, consequently, the requirement was transitioned to the Special Operations Force.

- A licensing effort to submit an ELA/PLA to the FDA for ***Clostridium botulinum* Toxoid, Pentavalent (Types A,B,C,D,E)** is currently underway. A pre- ELA/PLA meeting was held with the FDA on 17 April 1996. Animal studies for development of serological endpoints of protection in place of human efficacy studies were initiated at Battelle in 1996. A plan for clinical studies to determine immunogenicity for all five serotypes of the pentavalent toxoid was initiated. The protocol to conduct these studies was written, approved and submitted to the FDA. An FDA Advisory Committee Meeting for the development of serological endpoints of protection in place of human efficacy studies for the purpose of licensure, was held on 30 October 1996. USAMMDA hosted the 1996 Annual Meeting of the Interagency Botulism Research Coordinating Committee.

- Induction of volunteers for all cohorts into the Phase 2 safety and immunogenicity study for ***Clostridium botulinum* Type F Toxoid** was completed in 1996.

- The development contract for manufacture of **Clostridium Botulinum Type G** by the Center for Microbiology and Research was completed in September 1996.

- Management responsibility for the DOD contract with **Salk Vaccine Production Facility** passed from RAD IV to USAMMDA in 4QCY96.

- In 3QCY96, the **University of Maryland at Baltimore Vaccine Testing Facility** was tasked to conduct a Phase 1 clinical study of four dengue monovalent live-attenuated vaccine candidates. Ongoing are the Phase 1 Chikungunya Virus Vaccine Safety Study and a Phase 2 safety and immunogenicity study of Type F Botulinum Toxoid.

- Inventory items were reduced at the **Contingency Vaccine Storage Facility** at the National Center for Toxicological Research as a prelude to the expiration of the Interagency Agreement in CY97.

- Renovations of the **Michigan Biologic Products Institute** facility have been initiated in order to improve production facilities and meet establishment licensure regulatory requirements related to production of **Anthrax Vaccine, Adsorbed (AVA)**. Contractual arrangements are being negotiated for the continued storage, testing, and preparation for shipment of AVA and Pentavalent Botulinum Toxoid.

- **South Florida Drug Research Corporation** The one-year follow-up evaluation was completed on the 90 volunteers in the study, evaluating the tolerance of females and low-weight individuals to the doctrinal dose of pyridostigmine (30 mg every eight hours) for 21 days. A draft report of these results was delivered. Also, a final report was received for the results from the 21-day dosing period. A draft report was received for the second phase (sensitization) of the Topical Skin Protectant study.

- The competitive-procurement process was used to select the contractor for the **Non-Clinical Toxicology Contract** to run from 1997 through 2001. During CY96, 13 studies were initiated.

PROJECTIONS

- The Phase 2 treatment study for **WR 238,605** will be conducted. A Phase 2 prophylactic study will be initiated in Kenya. A drug interaction and the preclinical long term toxicology studies will be completed.

- The Phase 3 pivotal study for **Azithromycin** in Iran Jaya, Indonesia, will be completed. A prophylactic study against drug resistant malaria will be completed in Thailand. An end of Phase 3 meeting will be held with the FDA.

- The Phase 1 safety study for **Halofantrine** will be completed. A Phase 2 efficacy study will be initiated as well as drug interaction studies.

- It is anticipated that CRDA negotiations for **Tick-Borne Encephalitis Virus (GERMAN-BPL # 366) Vaccine** will be completed in 1QCY97 and an IND application prepared and submitted to the FDA. Initial clinical trials are planned for 3QCY97.

- **Tick-Borne Encephalitis Virus (AUSTRIAN-BPL# 335) Vaccine** will be again used in Bosnia for vaccination of an as-yet-undetermined number of U. S. soldiers.

- The study to determine whether **Topical Skin Protectant** protects against poison ivy dermatitis will be completed. The Chemistry, Manufacturing, and Controls section of the NDA will be completed. A customer test for **TSP** user acceptability will be conducted. Preparation of the NDA will be initiated.

- A special IPR will be conducted in which the Materiel Developer recommends that development be terminated or that further safety data be generated for the **Hantaan M-S (Vaccinia Vectored) Vaccine** through the Special Immunizations Program at USAMRIID.

- Sponsorship of the **Cholera Whole Cell Plus B Subunit Vaccine** will be turned over to SBL Vaccin AB as soon as the IPR is completed. The code for the pivotal efficacy trial in Peru will be broken.

- A CRDA with SBL Vaccin AB for further development of the **Enterotoxigenic *E. coli* (ETEC) Vaccine** will be finalized. A new lot of the vaccine, suitable for performing pivotal efficacy trials will be manufactured. A pivotal efficacy trial will be initiated in collaboration with the Israeli Defense Force.

- A PLA and ELA for **Argentine Hemorrhagic Fever Live Vaccine (AHF)** are in the latter stages of preparation and review. The final PLA/ELA package is anticipated for submission to the FDA in 4QCY97.

- The FDA-provided decision on the NDA for **Pyridostigmine** will be evaluated. Follow-up action, based on the decision of the FDA, will be undertaken, and the Acquisition Strategy for the Nerve Agent Pretreatment Pyridostigmine will be modified as necessary. Additional requests for information will be processed.

- Currently, the FDA is reviewing the **Hypertonic Saline Dextran** covariant meta-analysis data and Current Good Manufacturing Practice data that were added to the New Drug Application submission. FDA response is expected in 3QCY97.

- An IND for **Cyanide Pretreatment** will be filed with the FDA. Single-dose human safety and tolerance testing will begin 3QCY97 .

- A new lot of the **Campylobacter Vaccine** will be prepared by Autex Biologics, Inc., Gaithersburg, Maryland.

- Epidemiological data from several potential field sites will be evaluated to determine the optimal site to test the adjuvanted **Campylobacter Vaccine** in CY98.

- **Chikungunya Live Vaccine** development will be sustained only as an unfunded requirement.

- Tech transfer actions will be completed and a Special In-Process Review of **Schistosome Topical Antipenetrant** will be conducted in 3QCY97.

- **Rift Valley Fever, Live Vaccine** will be sustained only as an unfunded requirement.

- Chemical and Manufacturing information will be acquired from the manufacturer of **Arteether** and an Investigational New Drug Application will be submitted to U.S. FDA.

- The **Multichambered Autoinjector** will undergo the critical Clinical Bioequivalence Study. The Study Report will be evaluated and a decision on subsequent Acquisition Strategy will be made.

- The second Phase 1/2a safety study for **Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combinations** will be completed. A Phase 2b efficacy study will be initiated in Kenya.

- A Phase 1 safety study for the **Leishmania Skin Test Antigen** will be performed. A Milestone I In-Process Review will be conducted. A Phase 2 efficacy study will be initiated in Peru.

- A MS I/II IPR for the antileishmanial drug **WR 6026** will be completed in January 1997. The Phase 2 clinical trial in Brazil will be completed by August 1997.

- **Tularemia Live Vaccine** will continue to be used under IND status for immunization of at-risk personnel.

- The IND for **Botulism Immune Globulin $F(ab')_2$ Heptavalent Equine** will be submitted and a Phase 1 Clinical Safety Study will be conducted. The product will undergo quarterly stability testing.

- Funding reductions will delay initiation of a **Diagnostic Kit for Biological Warfare Agents** program. The Analysis of Alternatives document and an overall regulatory approval strategy will be finalized in CY97.

- For **Botulism Immune Globulin (Human),** in addition to annual stability testing, the FDA, Center for Biologics Evaluation and Research, has requested lots with potential for clinical use be retested for hepatitis C virus, HIV-1, and hepatitis B virus. This should be completed in CY97.

- It is anticipated that the majority of the effort required for the ELA/PLA for ***Clostridium botulinum*** **Toxoid, Pentavalent (Types A,B,C,D,E)** will be completed in

1997. Ongoing animal efficacy studies being conducted at Battelle will be completed in 1997. Additional studies recommended by the FDA Advisory Committee will be designed and conducted in 1997 if funding allows. Final blending of this product as an IND product will be completed in 1997. This meets the DOD current stockpile requirements for this product. Further production of this product is not anticipated at this time. Immunization of the chemical biological incident response (CBIR) Force with this product has been requested and planned for. It is anticipated that immunization will take place early in 1997.

- Phase 2 studies for ***Clostridium botulinum*** **Type F Toxoid** will be completed in 1997. It is anticipated that future development of this product will pass from USAMMDA to the Prime Contractor for development of biodefense vaccines.

- The current **Salk Vaccine Production Facility** contract will be closed out in CY97.

- The **University of Maryland at Baltimore Vaccine Testing Facility** will complete recruiting for all cohorts for the Phase 1 clinical study of 4 dengue monovalent live-attenuated vaccine candidates. Continuing will be a Phase 1 Chikungunya Virus Vaccine Safety Study and a Phase 2 safety and immunogenicity study of Type F Botulinum Toxoid.

- The **Contingency Vaccine Storage Facility** agreement at the National Center for Toxicological Research expires in CY97. The Joint Program Office for Biological Defense will determine if this agreement should be extended.

- **Michigan Biologic Products Institute** is currently the only responsible establishment licensed to manufacture **Anthrax Vaccine Adsorbed (AVA)** in the United States. Management of related contracts is anticipated to be a U.S. Army Medical Materiel Agency (USAMMA) responsibility once establishment and production scale-up issues have been resolved.

- Tasks will be initiated on the **Non-Clinical Toxicology Contract**. Two anticipated tasks will be a Segment III Study on WR 242511, a potential anticyanide drug, and a 2-year Carcinogenicity Study of WR 238605, a potential antimalarial drug.

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QUALITY ASSURANCE OFFICE (QAO)
QUALITY ASSURANCE AND REGULATORY AFFAIRS

INTRODUCTION

The Quality Assurance Office (QAO) supports the Project Management Divisions. The Office ensures quality and acceptability of safety and efficacy study data, control processes, manufacturing data and regulatory documentation for submission to the Food and Drug Administration (FDA) in support of product approval. Although teamwork and close coordination with Divisions are essential, the team provides this support function independently, reporting directly to the Director.

MILITARY RELEVANCE

The DOD, through The Surgeon General, U.S. Army, has determined that certain pharmaceutical, biological and device products are essential for protection of the warfighter and is committed to obtaining FDA approval documenting safety and efficacy of the products. The Quality Assurance (QA) and Regulatory Affairs (RA) programs provide essential monitoring of clinical studies and regulatory advice leading to generation of data with the necessary integrity to support product approval.

OBJECTIVES

The QAO has drafted the following objectives: 1) Creation of an environment receptive to the needs and requirements of the product development process; 2) Streamlining and standardization of the product development process by provision of quality assurance and regulatory affairs guidance; 3) Providing on-site training and monitoring; and, 4) Forging cooperation with allied government agencies and industry.

MAJOR ACCOMPLISHMENTS

- Expanded Regulatory Affairs role after the addition of a RegulatoryAffairs Specialist in early 1996. The QAO leadership transitioned smoothly in July. Two staff members successfully completed the Intermediate Systems Acquisition Course, and several members improved qualifications through attendance at Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP) courses. Personnel turbulence continues to affect operations as a seasoned Quality Assurance Specialist transferred to a position outside of USAMMDA. We are currently recruiting for this position.

- Cooperated with industry, Federal Regulatory and military agencies, Project and Product Managers and military laboratories in manufacturing aspects, planning and development of study protocols, and/or in trial monitoring of eight of the top fifteen priority products on the Mission Area Materiel Plan (MAMP). Equivalent activities were also performed on priority biological defense products not listed on the MAMP. Examples include the Reduced Schedule Anthrax Vaccine, Botulism Immune Globulin F (AB')2 Heptavalent (Equine), Botulinum Toxoid Type F, Nerve Agent Pre-Treatment Pyridostigmine and Botulinum Pentavalent (ABCDE) Toxoid. Audits have resulted in marked improvement in recordkeeping, which reduces regulatory agency requests for additional information and speeds the approval process.

- Provided quality assurance and regulatory affairs review of a major New Drug Application (NDA) submission for Pyridostigmine Bromide for protection of troops against nerve agents.

- Briefed and provided written reports to product managers on audit findings from over 50 specific monitoring visits and activities both in the United States and abroad. (See Tab 1 for Visit and Activity Schedule.) Out-briefings following in-life audits were specifically tailored to serve as learning experiences regarding regulatory requirements for field investigators. Formal presentations regarding *Overview of Regulatory Requirements* and *Recommended Standard Operating Procedures* for clinical studies were made before the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Walter Reed Army Institute of Research (WRAIR) study investigators/study coordinators groups.

- Developed and refined a standardized audit checklist annotated with appropriate regulation citations. This study site monitoring tool is used as an evolving system to assess the progress of a clinical trial and to equip the investigators, product managers and study coordinators with a list of the essential documents needed to complete a study. The audit tool was widely disseminated via the USAMMDA Internet home page. In addition, a draft guidance document for validation of computer software and hardware used in data collection, storage and manipulation in clinical trials was also developed and offered to investigators.

- Contributed in the smooth transition of the technical based product Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combinations to advanced development.

- Two staff members have been responsible for managing the review, completion and timely submission to the FDA of all required documents and reports generated by technology base research conducted on human subjects.

- Three staff members served as the USAMRMC points of contact and liaison for the Presidential Advisory Committee (PAC) on Gulf War Veterans' Illnesses and related issues during its active 1996 schedule.

- Represented the USAMMDA on the task force for establishment of a Technology Base Investigational New Drug management group to oversee quality assurance and regulatory affairs aspects of Medical Materiel Pre-development Studies involving human subjects. A QA staff member has also become an active member of the Human Subjects Research Review Board (HSRRB) Subcommittee for Review of Materiel List Plans and Protocols.

- Two QA members served as Contracting Officer's Representatives (COR) for the EER Regulatory Affairs Contract supporting numerous product development activities via contract/subcontract specialists. Technical knowledge of quality assurance and regulatory affairs is provided to assure that contract tasks are planned and carried out according to needs and specifications. This activity also serves as a vital link integrating the QAO to specific current and prospective product development activity in the USAMMDA Project Management Divisions.

PROJECTIONS

- Increase involvement as a vital support element for product development within the USAMMDA. Several continental United States (CONUS) and outside continental United States (OCONUS) monitoring visits are currently planned for early 1997, and increased emphasis will be placed upon cooperation and training with the QA monitoring function.

- Expand Internet information and education links to all study sites world-wide.

- Increase responsibility for Tech Base Investigational New Drug (IND) studies involving human subjects with emphasis not only on administrative oversight but also QA services in Good Clinical, Laboratory, and Manufacturing Practices required in the developmental process. It is anticipated that two additional qualified Quality Assurance personnel will be required to provide the manpower needed for this added responsibility.

- Create a new information and regulatory guide packet for study investigators and staff. Implement a system for periodic review and update of this information packet.

Visit and Activity Schedule for the Quality Assurance Office for CY 96

Date	Product	Site/Travel	Activity
JAN	Azithromycin Drug	NA	Protocol Review
	E.Coli Heat Labile Toxin	NA	Protocol Review
	Bot F Toxoid Vaccine	Lincoln, NE	Pre-study Visit
	E.Coli Heat Labile Toxin	USAMRIID	Mid-study Audit
	Antileishmanial WR6026	Vitoria, Brazil	Mid-study Audit
FEB	Azithromycin Drug	NAMRU-2, Indonesia	Pre-study Visit
	Bot F Toxoid Vaccine	College Park, MD	Mid-study Audit
	Halofantrine Drug	Georgetown, Wash DC	Mi-study Audit
	Halofantrine Drug	Miami, FL	Close-out
	Topical Skin Protectant	Miami, FL	Close-out
	WR238605 Antimalarial	Miami, FL	Close-out
	Pyridostigmine Bromide	Miami, FL	Close-out
	Bot F Toxoid Vaccine	College Park, MD	Mid-study Audit
	Oral ETEC Vaccine	NA	Protocol Review
	Cholera, Oral Vaccine	Lima, Peru	Mid-study Audit
MAR	Azithromycin Drug	AFRIMS, Thailand	Pre-study Visit
	Halofantrine Drug	Georgetown, Wash DC	Mid-study Audit
	Ribavirin Drug	Korea	Mid-study Audit
APR	Bot F Toxoid Vaccine	College Park, MD	Mid-study Audit
	TSP/Heat Exchange	USARIEM	Close-out
	WR238605 Antimalarial	NA	Protocol Review
MAY	WR238605 Antimalarial	USAMRIID	Close-out
	Bot IG F (AB')2 (Equine)	NA	Protocol Review
	Bot (A-E) Toxoid Vaccine	NA	Protocol Review
		Battelle Memorial Institute, OH	GLP Pre-study Site Visit
	Cholera, Oral Vaccine	Lima, Peru	Mid-study Audit
	Campylobactor Vaccine	NA	Protocol Review
	Azithromycin Drug	NA	Protocol Review
	Emergency Use	NA	Protocol Review
	Bot IG F (AB')2 (Equine)		
JUN	Bot F Toxoid Vaccine	College Park, MD	Mid-study Audit
	Oral ETEC Vaccine	NAMRU-3, Egypt	Mid-study Audit
	Halofantran Drug	Georgetown, Wash DC	Mid-study Audit
JUL	Bot (A-E) Toxoid Vaccine	NA	Protocol Review
	Bot F Toxoid Vaccine	College Park, MD	Mid-study Audit
	Campylobacter Vaccine	USAMRIID	Initiation Audit
AUG	Bot F Toxoid Vaccine	College Park, MD	Mid-study Audit
	Pyridostigmine Bromide	Miami, FL	Close-out
	Bot (A-E) Toxoid Vaccine	Battelle Memorial Institute, OH	GLP Mid-study Site Evaluation
	RTS,S Vaccine (Tech-base)	WRAIR	Close-out
SEP	Topical Skin Protectant	Bethesda, MD	Mid-study Audit
	Azithromycin Drug	AFRIMS, Thailand	Mid-study Audit
	Bot (A-E) Toxoid Vaccine	NA	Protocol Review
	Antileishmanial WR6026	Vitoria, Brazil	Mid-study Audit
	RTS,S Vaccine	NA	Protocol Review
OCT	WR238605 Antimalarial	AFRIMS, Thailand	Mid-study Audit
	Azithromycin Drug	Irian Jaya, Indonesia	Mid-study Audit
	RTS,S Vaccine	WRAIR	Initiation Audit
NOV	Anthrax Vaccine	USAMRIID	Initiation Audit
	Bot F Toxoid Vaccine	College Park	Mid-study Audit
	Halofantrine Drug	Georgetown, Wash DC	Mid-study Audit
	Bot Toxoids; Staph Enterotoxin	Porton, England	CGMP Audit
DEC	Oral ETEC Vaccine	NAMRU-3, Egypt	Mid-study Audit
	WR 238605 Antimalarial	NA	Protocol Review

PROJECT MANAGEMENT SUPPORT DIVISION

INTRODUCTION

The Project Management Support Division (PMSD) provides financial, contractual, logistical, and administrative support to the two Project Management Divisions. The successful accomplishment of the project management division programs is inextricably linked to PMSD's performance in the following areas: a centralized program-wide administrative, Planning, Programming, Budgeting and Execution System (PPBES); operation of a business planning and execution information management system (Project Management Division Database (PMDD) and Product Management Database System (PMDS)); oversight and operation of major support contracts; preparation of product development and production contracts; coordination of the medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP); program development and defense through the Enhanced Concept Based Requirements System (ECBRS) cycle; integrated logistical support planning, MANPRINT and user test coordination support planning for products; personnel and property resource management actions; and management of Defense Acquisition Workforce training requirements for the USAMMDA staff. These responsibilities and capabilities enhance in-house and program-wide fiscal performance and improve resource accountability for materiel development throughout the AMEDD.

RESOURCES MANAGEMENT

- **Project Management Division Database (PMDD), Product Management Database System (PMDS), and Special Users Database System**: The enhancement of two database systems that assist the Project and Product Managers in planning and programming product development costs were completed. The PMDD system enables Project Managers to designate the Product Manager-product pairing; to allocate funds to specific products; and to print Business Plans, Information Papers, and other planning reports. The PMDS enables the Product Managers to identify planned activities/funding requirements associated with each of their products; to generate Business Plans, Information Papers, and other planning reports; and to view planned, committed, and obligated funds on reports. Through a transfer procedure, the PMDS planning data becomes the baseline data for the Financial Management System (FMS) and General Analysis/Priority System. Several new FMS reports that provide summary and detail business plan information and information on committed funds are available to the Budget Analysts. A Special Users Database System was developed to allow management and logistics personnel the ability to review planning and funding information for all products. Automated linking of the five systems provides

tremendous productivity gains for USAMMDA, as Project Managers, Product Managers, and Budget Analysts can react faster to changes in project plans and execution requirements and share updated plans with development partners in the laboratories and at contract sites. Training on PMDD, PMDS, and the Special Users system was conducted in March 1996 for all USAMMDA personnel who use any of the systems.

- **Project Management Support Contract**: The Project Management Support Division provided the Contracting Officer's Representative for the USAMMDA support contract with Cambridge Consulting Corporation. The contract provides Project and Product Managers with additional resources for the development of required documentation, cost estimates and analytical services in an efficient and timely manner. During this year, the majority of the tasks given to the contractor included cost estimations, analyses of alternatives, preparation of Milestone In-Process Review read-ahead packages, and market investigations. An effort was begun this year to update the USAMMDA automated financial management and program analysis software support programs to a graphical user interface style of program. One very interesting task this year was the collection of photographs, 35mm slides and other picture media for conversion of product images to a digital format for publication on the USAMMDA World-Wide Website at *"http://www.amedd.army.mil/usammda/."*

- **Medical Research, Development, and Acquisition (RDA) Mission Area Materiel Plan (MAMP)**: In 1994, the AMEDD Center and School (AMEDDC&S) took the lead in organizing and executing the AMEDD's MAMP. The 1996 Medical RDA MAMP was conducted by electronic mail (E-mail) during May 1996. The MAMP performed product assessments for evaluating USAMRMC Research and Development program with respect to medical-related combat requirements. Representatives from USAMMDA, AMEDDC&S, and USAMMA evaluated 39 products and formally assessed 35 products against 12 operational capability requirements (OCRs). The OCRs, based on AMEDD deficiencies, enhancements, and obsolescences, are weighed in terms of relative importance. A paired comparison technique was used to determine the relative weight of AMEDD OCRs used in the ranking process. This component integrated medical materiel with an OCR "fix" to pinpoint the highest payoff for advanced development efforts. Prevention was shown to be relatively more important than either treatment or evacuation. A value-added component, which measures regional applicability and level of care/intervention, determined the relative value to a field commander of keeping troops on line by factoring in preventive efforts, return to duty actions, or treatment in fixed facilities, against the probability of a product's use in one of the six Unified Command geographical regions. The evaluation process was further enhanced with the addition of morbidity and mortality concepts. A logistical confidence component is added to the scoring process to assess the logistical supportability (provisioning, shelf-life, size, transportability, environmental

requirements, durability, maintainability, and power requirements). The MAMP priority list is a fully integrated effort to develop a systematic, prioritized, long-range Research, Development, and Acquisition strategy for medical materiel acquisition. Results of the MAMP, Appendix C, were distributed to all interested parties. The MAMP results are used as a tool to guide program planning and execution.

INFORMATION MANAGEMENT

- **Automated Data Processing Support:** Plans are underway to upgrade the current local area network (LAN) to a Windows NT-based network. This will provide increased security, remote dial-in, and MEDCOM-wide compatibility. Electronic mail (cc:Mail) was upgraded to increase users' capabilities. Additional Pentiums and PowerMacs were procured to meet users' needs. Staff located in the shop area of Building 1054 were incorporated into the USAMMDA LAN. Color scanners and additional laptops have also been procured.

UNIT SUPPORT

FACILITY

- **Buildings:** 622 - 12,762 sq. ft.
  1054 -16,831 sq. ft.
  1056 - 1,603 sq. ft.

- **Changes to buildings during FY 96:**

622 - Power washing of the building. Reconfigured modular furniture in Pharmaceuticals & Applied Medical Systems Divisions.

1054 - Turned-in foundry equipment to create a display area for the AMTV and other products in development.

1056 - Released 1000 sq. ft., freed up by consolidation of USAMMDA and USAMRIID Visual Information activities to USAG.

- **Supply Requisitions:**

404 total requisitions
- 340 IMPAC
- 32 BPA
- 32 Other

$240,702.94 committed

- **Property Book Values:**

Oct 95 - 634 line items = $4,503,649

Sep 96 - 587 line items = $4,087,156

-47 -$ 416,493

HUMAN RESOURCES

- **Manpower:**

a. In February 1996, the USAMMDA and USAMRIID Visual Information mission and assets were consolidated at USAMRIID. That action disestablished the Information Management Branch and realigned the remaining personnel to the Project Management Support Division.

b. Reductions in funding, personnel and supported workload dictated a more efficient structure; therefore, in March 1996, the Biological Systems Project Management Division was disestablished and authorizations and personnel realigned to the Pharmaceuticals Systems Project Management Division, reducing the administrative overhead. The consolidated division provides efficient management control while more efficiently using staff available to manage product development.

c. A MEDCOM Manpower Requirements Validation Study was conducted in June 1996. Military requirements were reduced by 5 (a 24%reduction), and civilian requirements by 5 (a 9% reduction). Additionally, fifteen contractor requirements were validated.

d. The proposed September 1996 reduction in force (RIF), involving two individuals, was averted due to management reprogramming actions which avoided the need to reduce permanent staffing.

- **Personnel:**

a. There were two civilian accessions, three employees transferred, one employee was promoted, one individual retired, and one employee was dropped from the rolls due to disability.

b. Military personnel actions included two accessions, one retirement, and one transfer.

c. Civilian Awards:

23 exceptional performance evaluations
18 performance awards
9 Commander's Awards for Civilian Service
2 Time-Off Awards
1 Quality Step Increase

d. Military Awards:

1 Legion of Merit
2 Meritorious Service Medals
2 Army Commendation Medals

e. Mr. Cecil C. Hathaway and Mr. James R. Sampson were selected as members of the Army Acquisition Corps Corps Eligible Program.

f. Ms. Janice M. Cole, Ms. Linda J. Sheffer, and Ms. Yvonne K. Higgins were certified at Level II in the Army Acquisition Workforce (AAW).

- **Key Personnel**:

Position	Name	Date
Commander	COL G.E. Lewis, Jr.	01 Jan 96 to 31 Aug 96
Director	Dr. J.H. Nelson	01 Sep 96 to 31 Dec 96
Deputy Commander	LTC J.A. Gere	01 Jan 96 to 31 Dec 96
Project Manager, AMSPMD	Dr. J.H. Nelson	01 Jan 96 to 31 Aug 96
Acting Project Manager	MAJ T.L. Syvertson	01 Sep 96 to 31 Dec 96
Project Manager, PSPMD	Dr. R.E. Clawson	01 Jan 96 to 31 Dec 96
Chief, PMSD	Mr. W.R. Ferguson, Jr.	01 Jan 96 to 31 Dec 96
Chief, Quality Assurance Office	LTC M. C. Burman	01 Jan 96 to 02 Aug 96
	LTC D.K. Feil	03Aug 96 to 31 Dec 96
Administrative Officer	Ms. D.W. Albright	01 Jan 96 to 31 Dec 96

- **Strength**: As of 31 December 1996:

	Military	Civilian	Contractors	Total
Required	16	51	15	82
Authorized	10	42	0	52
Actual	10	39	0	49

FISCAL PERFORMANCE

- **In-House**: In FY96, USAMMDA's in-house fiscal execution exceeded the USAMRMC disbursement target by 31 percent. Obligations were less than 2% below the established target.

	Allotment	Obligations	Disbursements
Fiscal 1996 Dollars ($000)	4,322	4,231	3,537
Target		100	51
Actual (%)		98	82

- **Program Wide:** Disbursements exceeded the target established for the FY96 total laboratory program, and laboratory obligations were within 1.5% of target. Performance in the command-wide development program fell below the target levels, attributable to significant delay in awarding the TSP development contract and delays in OCONUS studies. However, total program execution exceeded the percentage levels reached in FY95 in both obligations and disbursements. Fiscal execution performance at the project level is provided in Appendix E.

	Allotment	Obligations	Disbursements
Fiscal 1996 Dollars ($000)	18,139	17,001	8,332
Target		100	51
Actual (%)		94	46

INTEGRATED LOGISTICS PLANNING

- **Integrated Logistics Support and MANPRINT Documentation**: The following Integrated Logistic Support Plans (ILSP) were prepared in support of Milestone IPRs for USAMMDA products.

TYPE	PRODUCT
MS I	Antimalarial Drug, Arteether
MS I/II	Malaria Spf66 Blood Stage Vaccine
MS I/II	Armored Treatment and Transport Vehicle
MS II	Antimalarial Drug, Azithromycin
MS II	Topical Skin Protectant
Special IPR	Antimicrobial Dermal Dressing
Special IPR	Shigella E.coli Vector for S. Flexneri Vaccine
Special IPR	Whole Cell, Recombinant B Subunit Cholera Vaccine

- **Other Product-Specific Documents**:

PRODUCT	DOCUMENT
Field Medical Oxygen Generating and Distribution System	System MANPRINT Management Plan
	Integrated Program Summary
	Integrated Program Assessment
Hepatitis A Vaccine	Transition Documentation
Haantan Vaccine	Integrated Logistic Support Plan
Venezuelan Equine Encephalitis Infectious Clone Vaccine	Integrated Logistic Support Plan
Improved Anthrax Vaccine	Integrated Logistic Support Plan
Antileishmanial Drug, WR6026	Integrated Logistic Support Plan
Leishmanial Skin Test	Integrated Logistic Support Plan

- **Integrated Product Team (IPT) and Working Group Support:**
  - Tri-Service Theater Medical Information Program (TMIP) Joint Working Group
  - Rewrite of AR 40-60, AMEDD Acquisition Policy Development
  - Information Management IPT
  - Field Oxygen IPT
  - Artificial Intelligence/Expert Systems Working Group
- **General Logistics/Acquisition:**
  - Created and maintained USAMMDA World-Wide Website at http://www.amedd.army.mil/usammda/
  - Contracting Officer Representatives for three contracts (Pathology Associates, International; Cambridge Consulting Corporation; Guild Associates, Inc.).
  - Generated safety data package for ATTV safety release.

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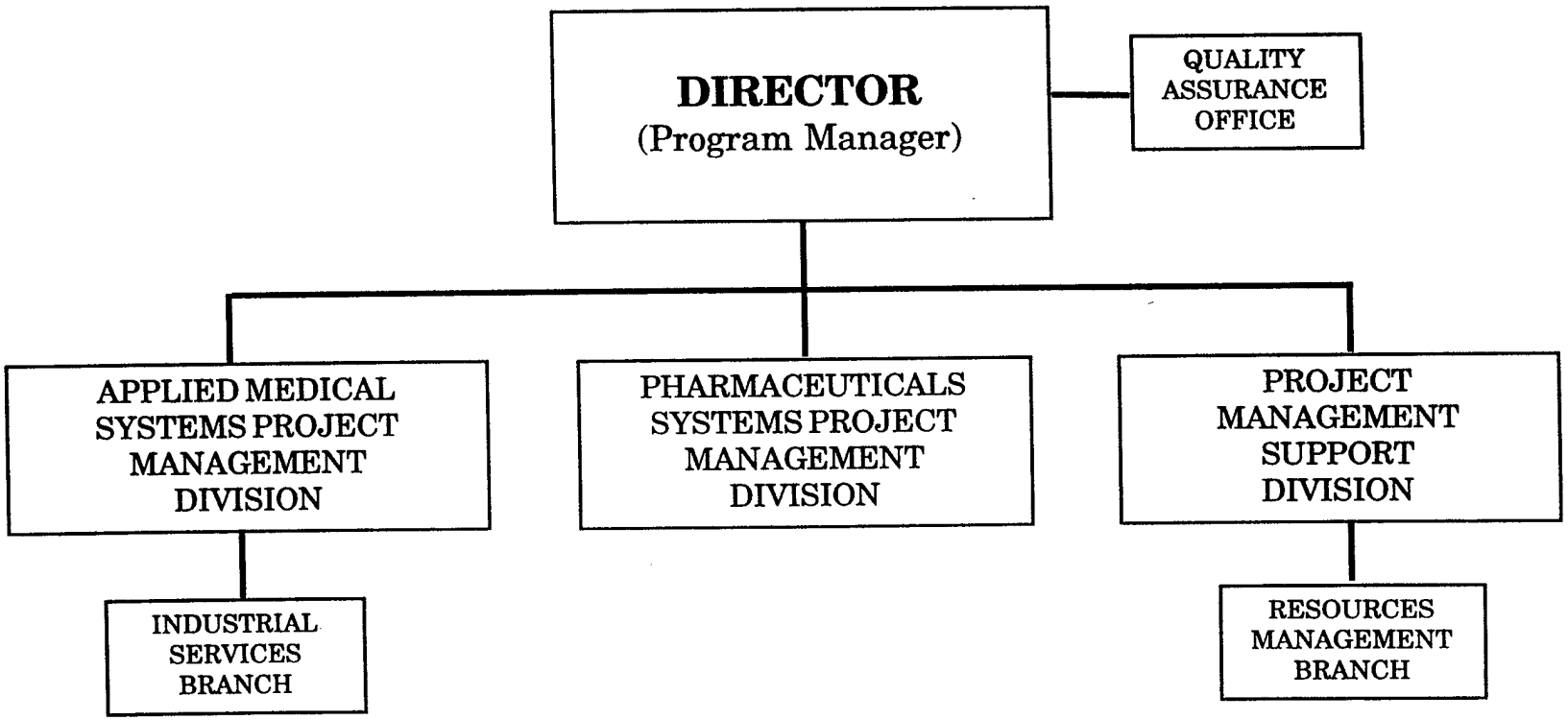
APPENDIX A

ACRONYMS

AMEDD	Army Medical Department
AMSPMD	Applied Medical Systems Project Management Division
CAMR	Centre for Applied Microbiology and Research
cGMP	Current Good Manufacturing Practices
CRDA	Collaborative Research and Development Agreement
CY	Calendar Year
DARPA	Defense Advanced Research Project Agency
DEET	N,N-Diethyltoluamide
DOD	Department of Defense
DMSB	Defense Medical Standardization Board
ECU	Executive Control Unit
ELA	Establishment License Application
FDA	Food and Drug Administration
FMS	Financial Management System
FY	Fiscal Year
GAPS	General Analysis/Priority System
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
ILSP	Integrated Logistic Support Plans
IND	Investigational New Drug Application
IPR	In-Process Review
IPT	Integrated Product Team
LOX	Liquid Oxygen
MAMP	Mission Area Materiel Plan
MBPI	Michigan Biologics Products Institute
MDPH	Michigan Department of Public Health
MS	Milestone
NDA	New Drug Application
NDI	Nondevelopment Item
NMRI	Naval Medical Research Institute
OCR	Operational Capability Requirements
ORD	Operational Requirements Document
PAC	Presidential Advisory Committee
PLA	Product License Application
PMD	Project Management Division
PMDD	Project Management Division Database
PMDS	Project Management Database System
PMSD	Project Management Support Division
PPBES	Planning, Programming, Budgeting and Execution System

PSPMD	Pharmaceutical Systems Project Management Division
QA	Quality Assurance
RDA	Research, Development and Acquisition
SBIR	Small Business Innovation Research
USAARL	U.S. Army Aeromedical Research Laboratory
USAMEDDC&S	U.S. Army Medical Department Center and School
USAMMA	U.S. Army Medical Materiel Agency
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USDA	U.S. Department of Agriculture
USNMRDC	U.S. Navy Medical Research and Development Command
UT	User Testing
WRAIR	Walter Reed Army Institute of Research

United States Army Medical Research and Materiel Command
United States Army Medical Materiel Development Activity



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APPENDIX C

PROGRAM PRIORITIZATION MAMP LIST

PRODUCT	1996 AMEDD PRIORITY
Antimalarial Drug, WR238605	1
Antimalarial Drug, Azithromycin	2
Low Temperature Sterilizing System	3
Antimalarial Drug, Halofantrine Prophylactic	4
Detoxified LPS-OMP Meningococcal Group B Vaccine	5
Tick-borne Encephalitis Vaccine	6
Topical Skin Protectant	7
Hantaan M-S (Vaccinia Vectored) Vaccine	8
Cholera Whole Cell Plus B Subunit Vaccine	9
ETEC Whole Cell, Recombinant B Subunit Vaccine	10
Argentine Hemorrhagic Fever Live Vaccine	11
Nerve Agent Pretreatment Pyridostigime	12
Hypertonic Saline Dextran	13
Cyanide Pretreatment	14
Campylobacter Vaccine	15
Chikungunya Live Vaccine	16
Schistosome Topical Antipenetrant	17
Self-Contained Ventilator	18
Rift Valley Fever Live Vaccine	19
Far Forward Suction Apparatus	20
Armored Ambulance	21
Field Triage Light	22
Shigella Flexneri Sc602	23
Antimalarial Drug, Arteether	24
Medical/Dental Filmless Imaging System	25
Intraosseos Infusion Device	26
Nerve Agent Antidote, Multichambered Autoinjector	27
Leishmania Skin Test	28
Life Support System, Trauma and Transport	29
Antileishmanial Drug, WR6026	30
Topical Antileishmanial Drug, Paromomycin	31
Thawed Blood Processing System	32
Field Anesthesia Machine	33
Microencapsulated Cephalosporin	34
Azithromycin (Scrub Typhus)	35

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APPENDIX D

PROJECT MANAGEMENT DIVISION PRODUCT LISTING

APPLIED MEDICAL SYSTEMS

- Advanced Surgical Suite for Trauma Casualties (AZTEC)
- Armored Medical Treatment Vehicle (AMTV)
- Blower, Lightweight, Ancillary for Chemical Protective Patient Wrap
- Combat Stress Analysis System (CSA)
- Electrochemical Sterilization System (ESS)
- Expert System for Trauma Management (ESTM)
- Far Forward Suction Apparatus (FFSA)
- Field Anesthesia Machine (FAM)
- Field Triage Light (FTL)
- Intraosseous Infusion Device (IID)
- IV Fluids Warmer (IVFW)
- Life Support for Trauma and Transport (LSTAT)
- Liquid Oxygen Production, Storage and Distribution System (LOPSDS)
- Low Temperature Sterilizing System (LTSS)
- Medical/Dental Filmless Imaging System (MDFIS)
- Portable Field Oxygen Concentrator (PFOC)
- Self Contained Ventilator (SCV)
- Thawed Blood Processing System (TBPS)
- Warfighter Personnel Status Monitor (WPSM)

PHARMACEUTICALS SYSTEMS

- Antimalarial Drug, Arteether
- Antimalarial Drug, Azithromycin
- Antimalarial Drug, Halofantrine, Prophylactic
- Antileishmanial Drug, WR 6026
- Antimalarial Drug WR 238,605
- Antimicrobial Dermal Dressing (ADD)
- Argentine Hemorrhagic Fever (AHF) Live Vaccine
- Botulinum Toxoid, Pentavalent (Types A,B,C,D,E)
- Botulinum Type F Toxoid
- Botulinum Type G Toxoid
- Botulism Immune Globulin $F(ab')_2$ Heptavalent Equine
- Botulism Immune Globulin (Human)
- Cyanide Pretreatment (CP), WR242511
- Campylobacter Vaccine

- Cell Culture Derived Vaccinia - Live Vaccine
- Chikungunya Live Vaccine
- Cholera Whole Cell Plus B Subunit Vaccine
- Detoxified LPS-OMP Meningococcal Group B Vaccine
- Diagnostic Kit for Biological Warfare Agents
- E coli Vectored S. flexneri Shigella Vaccine
- Enterotoxigenic E. coli (ETEC) Vaccine
- Hantaan M-S (Vaccinia Vectored) Vaccine
- Hypertonic Saline Dextran (HSD)
- Leishmania Skin Test
- Malaria Recombinant Vaccine (RTS,S) with Adjuvant Combinations
- Nerve Agent Antidote, Multichambered Autoinjector (MA)
- Nerve Agent Pretreatment, Pyridostigmine (NAPP)
- Q Fever CMR Extract Vaccine
- Ricin Toxoid Vaccine
- Rift Valley Fever Live Vaccine
- Schistosome Topical Antipenetrant (TAP)
- Tick-Borne Encephalitis Virus (GERMAN-BPL #366) Vaccine (TBE)
- Tick-Borne Encephalitis Virus (AUSTRIAN-BPL #335) Vaccine (TBE)
- Topical Skin Protectant (TSP)
- Tularemia Live Vaccine
- Vaccinia Immune Globulin (VIG)

APPENDIX E

FISCAL PROGRAM EXECUTION

DIRECT

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
808	3,598	100	93	100	13	100	64
836	2,593	98	85	89	31	95	62
837	1,155	66	66	99	0	98	1
993	3,719	99	59	70	20	80	34
Total 6.4	11,065	99	82	85	17	92	47
832	1,508	99	94	95	4	96	37
834	854	55	13	95	45	94	44
848	524	100	64	100	15	100	23
849	2,093	98	66	95	24	96	34
Total 6.5	4,979	97	77	96	22	96	35
Total Direct	16,044	99	81	89	19	93	43

REIMBURSABLE

Project	Allotment ($000)	PERCENT In-House OBL	In-House DISB	Extramural OBL	Extramural DISB	Total OBL	Total DISB
JPO-BD							
D/V	1,795	100	79	100	42	100	62
EMD	300	100	92	100	91	100	92
Total Reimbursable	1,095	100	81	100	47	100	67

TOTAL PROGRAM

D/V	12,860	99	81	87	20	93	49
EMD	5,279	97	79	96	24	96	39
Total Program	18,139	99	81	90	21	94	46